Journal of the American Osteopathic Association
Index to Volume 88

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January	1-134
February	135-286
March	287-444
April	445-565
May	566-690
June	691-818
July	819-940
August	941-1048
September	1049-1160
October	1161-1320
November	1321-1436
December	1437-1584

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MEDI-NOTES includes entries by month, with subjects and pagination.

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Author index

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Abramsohn, Lee: See Tarnopolsky, Rafael, jt. author
Alter, John: Rob and Smith's Operative surgery of the ear, 81-BR
—Manual of otolaryngology: Head & neck therapeutics, 546-BR
—Logan Turner's Diseases of the nose, throat and ear, 1301-BR
Ashley, Liz, and Stallings, James O.: End-to-side nerve flap for treatment of painful neuroma: A 15-year follow-up, 621*
Badia, Carl Della: 1987 Year book of obstetrics and gynecology, 675-BR
Bailin, Gary: Essentials of biochemistry, 800-BR
Baker, Helen H.: See Raub, Daniel J., jt. author
—See Ward, Douglas, jt. author
Barnish, Michael, and Condoluci, David V.: New Jersey's approach to AIDS, 1091*
Barnum, Grant M., Kurtz, Terrance O., and Hoff, Gary L.: Hemophilus influenzae pericarditis in an adult, 1519*
Barsky, Vivian M.: See Kolman, Stanley D., jt. author
Bartizal, Kenneth F.: See Kitz, Dennis J, jt. author
Bartkowski, Donald P., Levesque, Paul H., and Hoeffer, Richard A. Jr.: Method of obtaining chronic biliary tree access for long-term management of Oriental cholangiohepatitis: Report of a case, 1015*
Bates, Bruce P., Bates Charlotte K., and Tolstrup, Karen: Selection criteria in postgraduate osteopathic medical education, 391*
Bates, Charlotte K.: See Bates Bruce P., jt. author
Belkoff, Laurence H., and Finkelstein, Leonard H.: Combined transurethral electroresection and neodymium:YAG laser therapy for obstructing prostatism, 1219*
Belsky, Daniel H.: See Halpren, Edward W., jt. author
Benedetto, Joseph C. and Liszewski, Richard F.: Superior mesenteric arteriovenous fistula: Case report and literature review, 517*
Bennett, Joseph: See Norman, Robert A., jt. author
Benson, Don M., Shepherd, Steven R., and Dash, Bernard: Idiopathic thrombocytopenic purpura in a patient with Laurence-Moon-Bardet-Biedl syndrome, 779*
Biery, Daniel L: Endoscopic biliary tract stent—procedure of choice, 599-L
Bleicher, Jeffrey M.: See Nugent, Charles A., jt author
—The role of hyperlipidemia therapy in preventive care, 1255*
Blend, Michael J, and Francis, Kevin J.: Recommendations on limits for exposure to ionizing radiation, 540-BR
Boesler, David R.: See Ellestad, Stephen M., jt. author
Bowden, Boyd W.. The science and practice of intermedullary nailing, 917-BR
Bracken, Richard H.: See Smith, Gregory H., jt. author
Brown, Virgil W.: The cholesterol hypothesis and the value of intervention, 859*
Burandt, Timothy M., and Jarski, Robert W.: Small-bowel obstruction by adhesions secondary to caval perforation by Greenfield vena cava filter, 1239*
Burdick, J.R., and Sottile, William: Comparison of five latex agglutination kits for detecting group A streptococcal antigen, 219*
—Fundamentals of medical bacteriology and mycology, 921-BR
Butterworth, Mary L.: Practical anesthetic pharmacology, 266-BR
—Intravenous anesthesia and analgesia, 1037-BR
Calabrese, Leonard H: See D'Alonzo, Gilbert E., jt. author
—Kelley, Dennis: The physician's role in the prevention of AIDS, 877*
Calabria, J.T.: General surgery: Review and assessment, 539-BR
Campbell, Robert: AIDS: The general practitioner's concern, 371*
Cavalieri, Thomas A.: Geriatric curricula needed, 582-L
Chapman, Dudley J: Current obstetric & gynecologic diagnosis & treatment, 266-BR
—Dewhurst's Textbook of obstetrics and gynaecology for postgraduates, 539-BR
—Drug use in pregnancy, 920-BR
Chester, Willie James, and Thornburg, John E.: Jejunal diverticulosis: Report of a case and review of the literature, 511*
Cifala, John A.: Treatment with interferential current, 805-BR
Clark, James R.: The radiology of joint disease, Vol 2., 800-BR*
Cohen, Murray H.: Disorders of the liver, 264-BR
Condoluci, David V.: See Barnish, Michael, jt. author
Conte, Eugene T: Dermatology in general medicine: Vols I and II, 805-BR
Cortese, Anthony J.: Labor and delivery: Impact on offspring, 913-BR
Costin, J. Richard: Principles of surgical technique: The art of surgery, 1036-BR
Coussens, Wayne R.: See Henley, Charles E., jt. author
D'Alonzo, Gilbert E., and Calabrese, Leonard: AIDS: A challenge for osteopathic physicians, 93-E
—See Krachman, Samuel, jt. author
—See Pohil, Richard, jt. author
Daly, Stephen, See Freed, Nathan, jt. author
Dash, Bernard: See Benson, Don M., jt. author
Dekker, Anthony H.: The impact of AIDS in the pediatric and adolescent populations, 629*
—Response, 1064*
Deem, Bruce: See Norman, Robert A., jt. author
Denbow, Carl Jon, and Feeck, Richard: The many meanings of "holistic medicine", 15-L
Diamond, Seymour: See Freitag, Frederick G., jt. author
Di Marcangelo, Mark T: Paul and Juhl's Essentials of radiologic imaging, 81-BR
Doublestein, Gary L.: See Irving, W. Lee, jt. author

Journal of the American Osteopathic Association
Index to Volume 88

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November	1321-1436
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Abramsohn, Lee: See Tarnopolsky, Rafael, jt. author
Alter, John: Rob and Smith's Operative surgery of the ear, 81-BR
—Manual of otolaryngology: Head & neck therapeutics, 546-BR
—Logan Turner's Diseases of the nose, throat and ear, 1301-BR
Ashley, Liz, and Stallings, James O.: End-to-side nerve flap for treatment of painful neuroma: A 15-year follow-up, 621*
Badia, Carl Della: 1987 Year book of obstetrics and gynecology, 675-BR
Bailin, Gary: Essentials of biochemistry, 800-BR
Baker, Helen H.: See Raub, Daniel J., jt. author
—See Ward, Douglas, jt. author
Barnish, Michael, and Condoluci, David V.: New Jersey's approach to AIDS, 1091*
Barnum, Grant M., Kurtz, Terrance O., and Hoff, Gary L.: Hemophilus influenzae pericarditis in an adult, 1519*
Barsky, Vivian M.: See Kolman, Stanley D., jt. author
Bartizal, Kenneth F.: See Kitz, Dennis J, jt. author
Bartkowski, Donald P., Levesque, Paul H., and Hoeffer, Richard A. Jr.: Method of obtaining chronic biliary tree access for long-term management of Oriental cholangiohepatitis: Report of a case, 1015*
Bates, Bruce P., Bates Charlotte K., and Tolstrup, Karen: Selection criteria in postgraduate osteopathic medical education, 391*
Bates, Charlotte K.: See Bates Bruce P., jt. author
Belkoff, Laurence H., and Finkelstein, Leonard H.: Combined transurethral electroresection and neodymium:YAG laser therapy for obstructing prostatism, 1219*
Belsky, Daniel H.: See Halpren, Edward W., jt. author
Benedetto, Joseph C. and Liszewski, Richard F.: Superior mesenteric arteriovenous fistula: Case report and literature review, 517*
Bennett, Joseph: See Norman, Robert A., jt. author
Benson, Don M., Shepherd, Steven R., and Dash, Bernard: Idiopathic thrombocytopenic purpura in a patient with Laurence-Moon-Bardet-Biedl syndrome, 779*
Biery, Daniel L: Endoscopic biliary tract stent—procedure of choice, 599-L
Bleicher, Jeffrey M.: See Nugent, Charles A., jt author
—The role of hyperlipidemia therapy in preventive care, 1255*
Blend, Michael J, and Francis, Kevin J.: Recommendations on limits for exposure to ionizing radiation, 540-BR
Boesler, David R.: See Ellestad, Stephen M., jt. author
Bowden, Boyd W.. The science and practice of intermedullary nailing, 917-BR
Bracken, Richard H.: See Smith, Gregory H., jt. author
Brown, Virgil W.: The cholesterol hypothesis and the value of intervention, 859*
Burandt, Timothy M., and Jarski, Robert W.: Small-bowel obstruction by adhesions secondary to caval perforation by Greenfield vena cava filter, 1239*
Burdick, J.R., and Sottile, William: Comparison of five latex agglutination kits for detecting group A streptococcal antigen, 219*
—Fundamentals of medical bacteriology and mycology, 921-BR
Butterworth, Mary L.: Practical anesthetic pharmacology, 266-BR
—Intravenous anesthesia and analgesia, 1037-BR
Calabrese, Leonard H: See D'Alonzo, Gilbert E., jt. author
—Kelley, Dennis: The physician's role in the prevention of AIDS, 877*
Calabria, J.T.: General surgery: Review and assessment, 539-BR
Campbell, Robert: AIDS: The general practitioner's concern, 371*
Cavalieri, Thomas A.: Geriatric curricula needed, 582-L
Chapman, Dudley J: Current obstetric & gynecologic diagnosis & treatment, 266-BR
—Dewhurst's Textbook of obstetrics and gynaecology for postgraduates, 539-BR
—Drug use in pregnancy, 920-BR
Chester, Willie James, and Thornburg, John E.: Jejunal diverticulosis: Report of a case and review of the literature, 511*
Cifala, John A.: Treatment with interferential current, 805-BR
Clark, James R.: The radiology of joint disease, Vol 2., 800-BR*
Cohen, Murray H.: Disorders of the liver, 264-BR
Condoluci, David V.: See Barnish, Michael, jt. author
Conte, Eugene T: Dermatology in general medicine: Vols I and II, 805-BR
Cortese, Anthony J.: Labor and delivery: Impact on offspring, 913-BR
Costin, J. Richard: Principles of surgical technique: The art of surgery, 1036-BR
Coussens, Wayne R.: See Henley, Charles E., jt. author
D'Alonzo, Gilbert E., and Calabrese, Leonard: AIDS: A challenge for osteopathic physicians, 93-E
—See Krachman, Samuel, jt. author
—See Pohil, Richard, jt. author
Daly, Stephen, See Freed, Nathan, jt. author
Dash, Bernard: See Benson, Don M., jt. author
Dekker, Anthony H.: The impact of AIDS in the pediatric and adolescent populations, 629*
—Response, 1064*
Deem, Bruce: See Norman, Robert A., jt. author
Denbow, Carl Jon, and Feeck, Richard: The many meanings of "holistic medicine", 15-L
Diamond, Seymour: See Freitag, Frederick G., jt. author
Di Marcangelo, Mark T: Paul and Juhl's Essentials of radiologic imaging, 81-BR
Doublestein, Gary L.: See Irving, W. Lee, jt. author

Drake, Miles E. Jr.: See Kassiccieh, Daniel, jt. author
Drehsen, Christian G.: See Norman, Robert A., jt. author
Drouillard, Paul J., and Mrstik, Lloyd L.: Lumbar spinal stenosis associated with hypertrophied ligamentum flavum and calcium pyrophosphate crystal deposition, 1019*
Duerfeldt, William F.: Speaking out on homosexual health hazards beyond AIDS, 150-L
Dunn, Floyd E.: Clinical psychiatry, 917-BR
Edell, Steven L.: Radiologic-pathologic correlaton of musculoskeletal lesions, 275-BR
Ellestad, Stephen M., Nagle, Robert V., Boesler, David R., and Kilmore, Mearl A.: Electromyographic and skin resistance responses to osteopathic manipulative treatment for low-back pain, 991*
Feeck, Richard: See Denbow, Carl Jon., jt. author
Feinman, Larry Jay, Kolman, Stanley D., Minissale, Anthony A., and Barsky, Vivian M.: Colonic perforation and acute abdomen complicating antibiotic-associated pseudomembranous colitis, 1526*
Fierro, Vincent, and Freeman, Jeffrey S.: Choriocarcinoma-induced thyrotoxicosis: Report of a case and review of the literature, 525*
Finkelstein, Leonard H.: See Belkoff, Laurence H., jt. author
Fiorelli, Robert L., Kolman, Stanley D., Minissale, Anthony A., and Barsky, Vivian M.: Ovarian carcinoma presenting as pneumoperitoneum: Report of a case and review of the literature, 769*
Fischer, Roy L.: Atlas of pelvic surgery, 913-BR
Flynn, Joseph D. Jr.: See Wiener, Harvey M., jt. author
Fogarty, Joseph A.: Use of the vacuum extractor in the community hospital, 1106*
Foglietti, M.A., and Pandeya, N.K.: Reconstructive preprosthetic oral and maxillofacial surgery, 545-BR
Fox, Allan: See Kumar, Kusum, jt. author
—Francis, Kevin J.: See Blend, Michael J., jt. author
Freed, Nathan: Familial cancers, 231*
—Morley, Thomas P., Daly, Stephen, Giudice, James C., Steer, Robert A.: Aqueous heparin therapy: Intermittent *v* continuous administration, 1085*
Freeman, Jeffrey S.: See Fierro, Vincent., jt. author
Freitag, Frederick G., Diamond, Seymour, and Solomon, Glen D.: Reversible multiple cranial nerve palsies in temporal (giant cell) arteritis with normal sedimentation rate: Report of a case, 381*
—Psychiatric aspects of headache, 539-BR
—Magnetic resonance imaging, 1137-BR
Garcia, Mario D.: See Liang, Michael T.C., jt. author
Geiger, A. John: Don't "write off" alternative therapies, 1338-L
Geisler, Alan, See Zawisza, Michael J., jt. author
Gideon, David E., and Mulkey, James C.: Unilateral interfacetal dislocation in the lower cervical spine, 1223*
Ginsberg, Phillip C., Weiner, Perry, Klaus, Robert, Herring, William, and Goldberg, Scot E.: Emphysematous pyelonephritis, ureteritis, and cystitis: Report of a case, 895*
Giudice, James C.: See Freed, Nathan, jt. author
Goff, Walter B.: See Lubbers, Phillip R., jt. author
Goldberg, Barry B.: See Igidbashian, Vartan N., jt. author
Goldberg, Scot E.: See Ginsberg, Phillip C., jt. author
Goldsmith, Eric A., Gotfried, Edward A., and Joseph, J. Harris: Primary malignant melanoma involving the anorectum, 653*
Gotfried, Edward A.: See Goldsmith, Eric A., jt. author
Gruener, Gregory: See Toffol, Gilbert J., jt. author
Gulick, Peter: Review of current therapy in human immunodeficiency viral infections, 998*
Haas, Glenn E.: Traumatic arteriovenous fistula, 1109*
Haenel, Louis C.: See Halpren, Edward W., jt. author
Halpren, Edward W., Soifer, Neal E., Haenel, Louis C., Manara, Louis R., and Belsky, Daniel H.: Ketoacidosis secondary to oral ritodrine use in a gestational diabetic patient: Report of a case, 241*
Harrell, Jon F., Speilman, Daniel and Smith, Allan C.: Repair of a distal leg defect using the latissimus dorsi free flap, 1516*
Haspedis, Lynne and Wolf, David: Terbutaline in the treatment of preterm labor: A comparison of intravenous and subcutaneous administration, 489*
Hecker, Earl T.: Basic surgery, 264-BR
Hedayati, Hadi, and Zuzga, John J. Jr.: Osteoporosis: Current review, 1495*
Henley, Charles E., and Coussens, Wayne R.: The ability of family practice residents to diagnose depression in outpatients, 118*
Hernandez, Enrique: See Salk, Robert A., jt. author
—See Stever, Michael, jt. author
Herring, William: See Ginsberg, Phillip C., jt. author
Hintzman, Douglas: See Pandeya, N.K., jt. author
Hoefer, Richard A., Jr.: See Bartkowski, Donald P, jt. author
Hoefner, VC Jr.: See Steele, Karen M., jt. author
Hoff, Gary L: See Barnum, Grant M., jt. author
Hogan, Martin J.: See Wood, Douglas L., jt. author
Hunninghake, Donald B.: Current and new therapy for hypercholesterolemia, 865*
Igidbashian, Vartan N., Mitchell, Donald G., Merton, Daniel A., and Goldberg, Barry B.: Color Doppler imaging: An overview, 1273*
Irving, W. Lee, and Doublestein, Gary L.: Congenital amniotic band syndrome: Report of a familial recurrence, 891*
Isaak, Dale D.: See Kitz, Dennis, jt. author
Izuno, Cynthia: See Lubbers, Phillip R., jt. author
Jarski, Robert W.: See Burandt, Timothy M., jt. author
Johnson, Alan: See Lubbers, Phillip R., jt. author
Johnson, Jeffrey T: Comments on holistic medicine, 460-L
Johnson, Joyce M.: AIDS-related psychosocial issues for the patient and physician, 234*
—Neuropsychiatric sequelae of HIV infection, 494*
Johnston, William L.: Segmental definition: Part I. A focal point for diagnosis of somatic dysfunction, 99*
—Segmental definition: Part II. Application of an indirect method in osteopathic manipulative treatment, 211*
—Segmental definition: Part III. Definitive basis for distinguishing somatic findings of visceral reflex origin, 347*
Joseph, J. Harris : See Goldsmith, Eric A., jt. author
Kaczmarczyk, Joseph M., and Mansi, Michael L.: Alternate technique for cul-de-sac insufflation for laparoscopy, 755*
Kane, William M.: The physician and AIDS education in the schools, 635*
Kassicieh, Daniel, Drake, Miles E. Jr., Shuttleworth, Edwin C., and Rammohan, Kottil W.: Conduction aphasia following metrizamide myelography, 384*
Kebabjian, Stevon S.: A synopsis of anesthesia, 1036-BR
Kelley, Dennis: See Calabrese, Leonard H., jt. author
Ketterer, Mark W.: The thanatos syndrome, 668-BR
Kilmore, Mearl A.: See Ellestad, Stephen M., jt. author
Kimball, Judith Giencke: Hypothesis for prediction of stimulant drug effectiveness utilizing sensory integrative diagnostic methods, 757*
Kitz, Dennis J., Bartizal, Kenneth F., and Isaak, Dale D.: Cryptococcosis: Current status, 1003*
Klaus, Robert: See Ginsberg, Phillip C., jt. author
Kolman, Stanley D., Minissale, Anthony A., and Barsky, Vivian M.: Treatment of gastrocolic fistula with home total parenteral nutrition: Report of a case and review of the literature, 114*
—See Fiorelli, Robert L., jt. author
Kolarik, Dennis B.: Techniques in surgical casting and splinting, 679-BR
Koop, C. Everett: Physician participation needed in AIDS education, 92-E
Korr, Irvin M.: Medical education: The resistance to change, 1022*
Krachman, Samuel, and D'Alonzo, Gilbert E.: Acquired immunodeficiency syndrome and the health care worker, 749*
Kroenke, Kurt K.: See Wood, David R., jt. author
Kule, Sheldon: See Siebert, Marjorie M, jt. author
Kumar, Kusum, and Fox, Allan: Teaching laboratory medicine with a problem-solving approach, 899*
Kurtz, Terrance O.: See Barnum, Grant M., jt. author
Kushner, Marla D.: Preventing teenage suicide: The living alternative handbook, 1137-BR
Kushnick, Helen: A mother's viewpoint, 641*
Levesque, Paul H.: See Bartkowski, Donald P, jt. author
Liang, Michael T.C.: American College of Sports Medicine: Resource manual for guidelines for exercise testing and prescription, 1412-BR
Liang, Michael T.C., Garcia, Mario D., and McAllister, Loring: Effects of an exercise and stress management program on cardiac patient's psychosocial and vocational status: Preliminary study, 1209*
Licciardone, John C.: Clinical obstetrics: A public health perspective, 415-BR
Lindquist, Carl M.: Update guidelines for vaccinations in HIV-infected children, 1064-L
Liszewski, Richard F.: See Benedetto, Joseph C., jt. author
Lubbers, Phillip R., Izuno, Cynthia, Goff, Walter B., Johnson, Alan, and Sikes, Randle: Magnetic resonance imaging of pelvic masses complicating pregnancy, 1010*
Manara, Louis R.: See Halpren, Edward W., jt. author
Mann, Mary Pat, See Raub, Daniel J., jt. author
Mansi, Michael L.: See Kaczmarczyk, Joseph M., jt. author
Maple, Philip: See Pohil, Richard, jt. author
McAllister, Loring: See Liang, Michael T.C., jt. author
McBrayer, Craig: Peripheral vascular surgery, 1296-BR
McCarroll, Connie Jo., and Vogel, H. Lauren: Multiple brain abscesses treated with antibiotics: Report of a case, 657*
Meals, Robert L.: See Stankiewicz, Alan, jt. author
Mercola, Joseph M.: Private resources should share AIDS funding responsibility, 313-L
Merton, Daniel A.: See Igidbashian, Vartan N.
Meulendyk, John: Fear fuels attitudes toward gays, 582-L

Min, Kyung W.: See Tarnopolsky, Rafael, jt. author
Minissale, Anthony A.: See Kolman, Stanley D., jt. author
—See Fiorelli, Robert L., jt. author
Minkin, Sheldon R.: Moral judgments or AIDS education? 582-L
Mitchell, Donald G.: See Igidbashian, Vartan N., jt. author
Miyazawa, Kunio: See Salk, Robert A., jt. author
—See Stever, Michael, jt. author
Moloff, Alan L.: Redesigning the workplace prevents low-back injuries, 834-L
Morey, Lloyd W.: Need to distinguish good medicine from inappropriate health care, 704-L
Morley, Thomas P.: See Freed, Nathan, jt. author
Mrstik, Lloyd, L. See Drouillard, Paul J., jt. author
Mulford, D Kent: Computer training needed for students, 591-L
Mulkey, James C.: See Gideon, David E., jt. author
Nagle, Robert V.: See Ellestad, Stephen M., jt. author
Naheedy, Mohammed H.: See Toffol, Gilbert J., jt. author
Norman, Robert A., Bennett, Joseph, Drehsen, Christian G., and Deem, Bruce: Dermatofibroma protuberans: Report of a case, 245*
—Common problems in dermatology, 1132-BR
—Medical professionals' crusade for human rights, 591-L
—Pigmented lesions of the skin: Clinicopathologic correlations, 540-BR
—The body silent, 913-BR
—The breaking of bodies and minds: Torture, psychiatric abuse, and the health professions, 675-BR
Nugent, Charles A., Bleicher, Jeffrey M., and Plachetka, John R.: Labetalol in the treatment of elderly patients with mild essential hypertension, 359*
Olson, Christopher D.: Computerized clinical records for ambulatory patients, 1509*
Pandeya, N.K.: See Foglietti, M.A., jt. author
—Hintzman, Douglas: Essential of plastic, maxillofacial, and reconstructive surgery, 668-BR
Papadeas, Gregory G.: See Shadday, G. Jude, jt. author
Parrillo, Steven J.: Essentials of emergency medicine 77-BR
Pera, Abraham: Orthopedic radiology, 419-BR
—Computed cranial & spinal imaging: A practical introduction, 1301-BR
Perez, John F.: Bladder reconstruction and continent urinary diversion, 1412-BR
Perez, John F.: See Smith, Gregory H., jt. author
Phelps, Craig M.: Office management of sports injuries and athletic problems, 1132-BR
Plachetka, John R.: See Nugent, Charles A., jt. author
Pohil, Richard, Maple, Philip, and D'Alonzo, Gilbert: Diffuse lung infiltration in a homosexual man with AIDS, 1115*
Pulver, Vern B.: Immunocytochemistry: Modern methods and applications, 275-BR
Rammohan, Kottil W.: See Kassicieh, Daniel, jt. author
Raub, Daniel J, Baker, Helen H., and Mann Mary Pat: The McDaniel family: The impact of small-group clinical teaching early in the medical school curriculum, 123*
Redwine, John N.: Agreement on osteopathic CME requirements, 460-L
Reich, Margaret: A prescription for taking medicine properly, 1421-PHG
—Arthroscopy: A leg up on knee surgery, 132-PHG
—Dyslexia, a lesson in reading disabilities, 1317-PHG
—Ear disorders in children, 283-PHG
—Focusing on contact lenses, 1045-PHG
—Involuntary urine loss: Dispelling the myths, 1153-PHG
—Mysterious premenstrual syndrome (PMS), 935-PHG
—Sun raises skin cancer risks, 813-PHG
—Taking charge of your migraine, 561-PHG
—Taking the lid off eating disorders, 685-PHG
—The driving force of pacemakers, 441-PHG
—Undergraduate osteopathic medical education, 1377*
—US osteopathic medical school finances, 1383*
Rentz, Louis E.: Stroke, 415-BR
Reuther, George A.: AOA continuing osteopathic medical education, 1399*
Richards, David M.: TCOM strikes up anti-smoking accord, 313-L
Rongaus, Val A.: See Wehmann, Thomas W., jt. author
Rose, Norman: Principles of basic surgery practice, 419-BR
—Diagnostic patient studies in surgery, 1036-BR
—Roulier, Randolphe G.: Surgical application of laser, 1132-BR
Salk, Robert A., Hernandez, Enrique, and Miyazawa, Kunio: Management of immediate postcesarean section hemorrhage, 645*
Sesso, Donald J.: Interstitial lung disease, 808-BR
Shadday, G. Jude, Papadeas, Gregory G., Smith, Lori L.: The progression of osteopathic medicine internationally: A survey of America-trained DOs practicing abroad, 1095*
Sheldon, Stephen H.: Infant of the diabetic mother: Report of the 93rd Ross Conference on Pediatric Research, 804-BR
Shepherd, Steven R.: See Benson, Don M., jt. author
Shuttleworth, Edwin C.: See Kassicieh, Daniel, jt. author
Siebert, Marjorie M., Kule, Sheldon: Mitral valve prolapse—A pervasive condition of uncertain etiology, 1099*
Siehl, Donald: The shoulder: Surgical and nonsurgical treatment, 800-BR
Sikes, Randle: See Lubbers, Phillip R., jt. author
Smith, Allan C: See Harrell, Jon F., jt. author
Smith, Gregory H., Perez, John F., and Bracken, Richard H.: Acute torsion of the gallbladder, 1523*
Smith, Lori L.: See Shadday, G. Jude, jt. author
Soifer, Neil E.: See Halpren, Edward W, jt. author
Solomon, Glen D.: See Freitag, Frederick G., jt. author
Sottile, William: See Burdick J.R., jt. author
Speilman, Daniel: See Harrell, Jon F., jt. author
Stallings, James O.: See Ashley, Liz, jt. author
Stankiewicz, Alan, and Meals, Robert L.: Ultrasonic assessment of fetal growth: A computed-assisted protocol, 729*
Steele, Karen M., and Hoefner, VC. Jr.: Preplacement low-back screening for high-risk areas, 499*
—Author's reply, 834-L
Steer, Robert A.: See Freed, Nathan, jt. author
Stever, Michael, Hernandez, Enrique, and Miyazawa, Kunio: Laser vaporization of cervical intraepithelial neoplasia, 1269*
Suter, Robert E.: Hippocratic thought: Its relationship to and between Andrew Taylor Still and Sir William Osler, 1243*
Tarnopolsky, Rafael, Abramsohn, Lee, and Min, Kyung W.: Facial malignant melanoma in a 3-year-old child, 1231*
Theriault, Richard L.: Acquired immune deficiency syndrome: An overview, 109*
Thornburg, John E.: See Chester, Willie James, jt. author
Tobe, Edward H.: Pitfalls in the management of panic disorder, 507*
Toffol, Gilbert J., Gruener, Gregory, and Naheedy, Mohammed H.: Early-filling cerebral vein, 1007*
Tolstrup, Karen: See Bates, Bruce P., jt. author
Vogel, H. Lauren: See McCarroll, Connie Jo, jt. author
Voss, W.H., Detection, evaluation, and treatment of hypercholesterolemia in adults: Commentary on the National Cholesterol Education Program guidelines, 845*
Ward, Douglas, and Baker, Helen H.: Osteopathic postdoctoral education in transition, 1389*
Wehmann, Thomas W., Rongaus, Val A.: Delayed hydromediastinum after multilumen central venous catheterization, 1118*
Weinberg, Theodore: Endocrine pathology: A patient-oriented approach, 545-BR
Weiner, Perry: See Ginsberg, Phillip C., jt. author
Weis, Stephen E.: Lipoproteins and cholesterol: Biosynthesis and metabolism, 870*
Wiener, Harvey M., and Flynn, Joseph D. Jr.: Percutaneous cholecystostomy: Case Report and literature review, 251*
Wolf, David: See Haspedis, Lynne, jt. author
Wood, David R., and Kroenke, Kurt K.: Laboratory testing in a hypertension clinic: A reappraisal, 365*
Wood, Douglas L., and Hogan, Martin J.: Time use by trainees in medical education, 396*
Wyatt, William E.: Low-back injuries and osteopathic medicine: Practicing what we preach, 1338-L
Zawisza, Michael J., and Geisler, Alan: Spontaneous rupture of esophagus (Boerhaave's syndrome): Case report and literature review,

Subject index

The index includes subject entries for all original articles identified by an asterisk (*), editorials identified by the letter "E," letters by the letter "L," and patient health guide by the letters "PHG."

Editorials are also listed alphabetically by title under the heading EDITORIALS.

Entries for contents of medi-notes are listed under the heading MEDI-NOTES, then by month and page.

Entries for patient health guide are also listed alphabetically under the heading PATIENT HEALTH GUIDE.

Entries for book reviews and book notices (identified by "R" and "N" follow all entries under the letter "B"

A

ABDOMEN
superior mesenteric arteriovenous fistula: case report and literature review [Benedetto and Liszewski], 517*
ABSCESSES
multiple brain abscesses treated with antibiotics: report of a case [McCarroll and Vogel], 657*
ACCREDITATION
history of osteopathic medical education accreditation [AOA Editorial Department], 1371*
ACQUIRED IMMUNE DEFICIENCY SYNDROME
a mother's viewpoint [Kushnick], 641*
acquired immune deficiency syndrome: an overview [Theriault], 109*
acquired immunodeficiency syndrome and the health care worker [Krachman and D'Alonzo], 749*
AIDS: a challenge for osteopathic physicians [D'Alonzo and Calabrese], 93-E
AIDS-related psychosocial issues for the patient and physician [Johnson], 234*
AIDS: the general practitioner's concern [Campbell], 371*
diffuse lung infiltration in a homosexual man without AIDS [Pohil, Maple, and D'Alonzo], 1115*
JAOA provides ongoing AIDS education for physicians [D'Alonzo], 844-E
neuropsychiatric sequelae of HIV infection [Johnson], 494*
New Jersey's approach to AIDS [Barnish and Condoluci], 1091*
physician participation needed in AIDS education [Koop], 92-E
review of current therapy in human immunodeficiency viral infections [Gulick], 998*
the impact of AIDS in the pediatric and adolescent populations [Dekker], 629*
the physician and AIDS education in the schools [Kane], 635*
the physician's role in the prevention of AIDS [Calabrese and Kelley], 877*
the proper emphasis for AIDS education [Allen], 618-E
AMERICAN MEDICAL ASSOCIATION
AOA takes issue with AMA 'paranurse' proposal [Allen], 1077-E
AMERICAN OSTEOPATHIC ASSOCIATION
AOA takes issue with AMA 'paranurse' proposal [Allen], 1077-E
JAOA education issue highlights profession's growth [Williamson], 1369-E
osteopathic manipulative treatment [Allen], 1077-E
preventable hepatitis B remains health problem [Allen], 1480-E
the progression of osteopathic medicine internationally: a survey of America-trained DOs practicing abroad [Shadday, Papadeas, and Smith], 1095*
the proper emphasis for AIDS education [Allen], 618-E
AMNIOTIC BAND SYNDROME
congenital amniotic band syndrome: report of a familial recurrence [Irving and Doublestein], 891*
ANDREW TAYLOR STILL
Hippocratic thought: its relationship to and between Andrew Taylor Still and Sir William Osler [Suter], 1243*
ANEURYSM
superior mesenteric arteriovenous fistula: case report and literature review [Benedetto and Liszewski], 517*
ANGIOGRAPHY
early-filling cerebral vein [Toffol, Gruener, and Naheedy], 1007*
ANTIBIOTICS
multiple brain abscesses treated with antibiotics: report of a case [McCarroll and Vogel], 657*
ANUS
primary malignant melanoma involving the anorectum [Goldsmith, Gotfried, and Joseph], 653*
APHASIA
conduction aphasia following metrizamide myelography [Kassicieh, Drake, Shuttleworth, and Rammohan], 384*
ARTERIES
traumatic arteriovenous fistula [Haas], 1109*
ARTERITIS
reversible multiple cranial nerve palsies in temporal (giant cell) arteritis with normal sedimentation rate: report of a case [Freitag, Diamond, and Solomon], 381*

B

BACK
low-back injuries and osteopathic medicine: practicing what we preach [Wyatt], 1338-L
preplacement low-back screening for high-risk area [Steele and Hoefner], 499*
BILIARY TRACT
method of obtaining chronic biliary tree access for long-term management of Oriental cholangiohepatitis: report of a case [Bartkowski, Levesque, and Hoefer], 1015*
BOERHAAVE'S SYNDROME
spontaneous rupture of esophagus (Boerhaave's syndrome): case report and literature review [Zawisza and Geisler], 787*
BOWEL
small-bowel obstruction by adhesions secondary to caval perforation by Greenfield vena cava filter [Burandt and Jarski], 1239*
BRAIN
multiple brain abscesses treated with antibiotics: report of a case [McCarroll and Vogel], 657*

BOOKS

(All books listed in the book section are listed below, alphabetically, by author under subject classifications. "R" indicates a review; "N" indicates a book notice.)

Allergy

Rapp, Doris: Recognize and manage your allergies, 408-N

Anatomy

MacKinnon, Pamela C.B., and Morris, John F.: Oxford textbook of func tional anatomy: Thorax and abdomen. vol. II, 1301-N
Stern, Jack T.: Essentials of gross anatomy, 277-N
Twietmeyer, Alan T.: Regional guide to human anatomy: 81-N

Anesthesiology

Atkinson, R.S., Rushman, G.B., and Lee, J. Alfred: A synopsis of anaesthesia, 277-N, 1036-R
Logan Turner's Diseases of the nose, throat and ear, 1301-BR
Attia, Rafik R, Grugono, Alan W., and Domer, Floyd, R., eds.,: Practical anesthetic pharmacology, 266-R
Corssen, Guenther, Reves, J.G, and Stanley, Theodore H.: Intravenous anesthesia and analgesia, 1037-R

Arthritis

Banwell, Barbara, and Gall, Victoria, eds.: Physical therapy management of arthritis. Vol. 16, 1037-N

Bacteriology

Myrik, Quentin N, and Weiser, Russell S.: Fundamentals of medical bacteriology and mycology, ed. 2, 921-R

Biochemistry

Murray, Robert K., Granner, Daryl K., and Rodwell, Victor W.: Harper's Biochemistry, 405-N
Schumm, Dorothy E.: Essentials of biochemistry, 277-N , 800-R

Cancer

Gottlieb, Geoffrey J., and Ackerman, Bernard A.: Kaposi's sarcoma, 546-N

Cardiology

Heger, Joel W., Treister, Neil W., and Writer, Steven L.: Case studies in cardiology for the house officer, 1412-N
Zipes, Douglas P., and Rowlands, Derek J., eds.: Progress in cardiology, 1412-N

Cardiovascular system

AbuRahma, Ali F. and Diethrich, Edward B., eds.: Current noninvasive vascular diagnosis: 277-N
Brown, Kevin R., and Jacobson, Sheldon: Mastering dysrhythmias: A problem-solving guide, 546-N
Edmonds, John H. Jr.: ECG Stat! Hospital electrocardiography in urgent situations, 277-N
Fardy, Paul S., and Yannowitz, Frank G.: Cardiac rehabilitation, adult fitness, and exercise testing, 679-N

Mandal, Anil K., and Jennette, J. Charles: Diagnosis and management of renal disease and hypertension, 924-N
Millikan, Clark H., McDowell, Fletcher, and Easton, J. Donald: Stroke, 415-R
Paine, Robert: Generation and interpretation of the electrocardiogram, 1037-N
Stein, Emmanuel: Interpretation of arrhythmias: A self-study program, 546-N
Thaler, Malcolm S.: The only EKG book you'll ever need, 924-N
Yang, Sing San, Bentivoglio, Lambert G., Maranhao, Vladir, and Goldberg, Harry: From cardiac catheterization to hemodyromic parameters. ed. 3, 546-N
Yu, Paul N, and Goodwin, John F., eds.: Progress in cardiology, 679-N
Zipes, Douglas P., and Rowlands, Derek J, eds.: Progress in cardiology, 679-N

Dermatology

Fitzpatrick, Thomas B., Eisen, Arthur Z., and Wolff, Klaus, et al.: Dermatology in general medicine: Vols I and II, 81-N, 805-R
Greer, Kenneth E.: Common problems in dermatology, 1132-R
Krusinski, Paul A., and Flowers, Franklin P.: Life-threatening dermatoses, 546-N
Maize, John C., and Ackerman, A. Bernard: Pigmented lesions of the skin: Clinicopathologic correlations, 540-R

Embryology

Moore, Keith L.: Essentials of human embryology, 679-N

Emergency medicine

Rund, Douglas A.: Essentials of emergency medicine, 77-R

Endocrinology

Gabbe, S.G., and Oh., W., eds.: Infant of the diabetic mother: Report of the 93rd Ross Conference on Pediatric Research, 277-N, 804-R

Environmental medicine

Golos, Natalie, O'Shea, James F., and Waickman Francis J. with Golbitz, Frances Golos: Environmental medicine: A practical, participatory course/textbook—patients and professionals—for all who need to know how to diagnose and manage allergies, 405-N
Hershman, Jerome M.: Endocrine pathology: A patient-oriented approach, 545-R

Family medicine

Cera, Roselyn M., Vulanich, Nova N., and Brady, William A.: The head-injured patient: A family guide to assisting in rehabilitation, 408-N

Genetics

Reading, Chris M., and Meillon, Ross S.: Your family tree connection, 924-N

Health systems

Howard, Diane M., ed.: New business development in ambulatory care: Exploring diversification options, 679-N
Koff, Sondra Z.: Health systems agencies: A comprehensive examination of planning and process, 679-N
Leebov, Wendy, ed.: Service excellence: The customer relations strategy for health care, 679-N
Metzger, Norman: The health care supervisor's handbook. ed. 3, 679-N

Hepatology

Chopra, Sanjin: Disorders of the liver, 264-R

Hospitals

Abendshien, John: A guide to the board's role in strategic business planning, 1037-N
Howard, Diane M., ed.: New business development in ambulatory care; Exploring diversification options, 924-N
Koff, Sondra Z.: Health system agencies: A comprehensive examination of planning and process, 924-N
Orlikoff, James E, and Vanagunas, Audrone M.: Malpractice prevention and liability control for hospitals. ed. 2, 924-N
Pegels, C. Carl, and Rogers, Kenneth A.: Strategic management of hospitals and health care facilities, 679-N
Puckett, Ruby P., and Miller, Bonnie M.: Food service manual for health care institutions, 1988 edition, 924-N
Skurka, Margaret Flettre: Organization of medical record departments in hospitals. ed. 2, 924-N
Williams, Richard C.: Managing the hospital sales team, 679-N

Imaging modalities

Stark, David D., and Bradley, William G., Jr. ed. 1: Magnetic resonance imaging, 1137-R
Stevens, John M., Valentine, Alan R., and Kendall, Brian E.: Computed cranial & spinal imaging: A practical introduction, 1301-R

Immunology

Polak, Julia M., and Noorden, Susan Van: Immunocytochemistry: Modern methods and applications. ed. 2, 275-R
Righthope, Ian: The AIDS fighters: The role of vitamin C and other immunity-building nutrients, 924-N
Toledo-Pereyra, Luis H., ed.: Immunology essentials of surgical practice, 1301-N

Infectious disease

Conte, John E., and Barriere, Steven L.: Manual of antibiotics and infectious disease, 679-N
Mann, Ronald J.: Infections of the hand, 277-N

Internal medicine

Braunwald, Eugene, et al., eds.: Harrison's Principles of internal medicine: Companion handbook, 81-N
Burst, J. Willis, et al., eds.: Medicine for the practicing physician, 1140-N

Microbiology

Myrik, Quentin N., and Weiser, Russell S.: Fundamentals of medical bacteriology and mycology, 277-N

Nephrology

Glassock, Richard J.: Current therapy in nephrology and hypertension. ed. 2, 77-R

Neurology

Cowan, Maxwell, et al., eds.: Annual review of neuroscience, Vol 11, 924-N

Nutrition

Halpren, Seymour L., ed.: Clinical nutrition. ed. 2, 679-N
Passwater, Richard A.: Fish oils update: Latest research on marine lipids and their newly discovered health roles, 84-N
Shils, Maurice E., and Young, Vernon R., eds.: Modern nutrition in health and disease. ed. 7, 408-N
Yetiv, Jack Z., Popular nutritional practices: Sense and nonsense, 408-N

Obstetrics-gynecology

Friedman, Emanuel, and Neff, Raymond K.: Labor and delivery: Impact on offspring, 913-R
Mishell, Daniel R., Kirschbaum, Thomas, and Morrow, C. Paul, eds.: 1987 Year book of obstetrics and gynecology, 675-R
Niebyl, Jennifer R.: Drug use in pregnancy. ed. 2, 920-R
Pernoll, Martin L., and Benson, Ralph C., eds.: Current obstetric & gynecologic diagnosis & treatment. ed. 6, 266-R
Sachs, Benjamin P., Acker, and David: Clinical obstetrics: A public health perspecitve, 415-R
Whitfield, C.R., ed.: Dewhurst's Textbook of obstetrics and gynaecology for postgraduates, 539-R

Occupational health

Himmelstein, Jay S., and Pransky, Glenn S., eds.: Worker fitness and evaluations, 924-N

Of general interest

Alter, Michael J.: Science of stretching, 546-N
Borysenko, Joan: Minding the body, mending the mind, 1412-N
Byers, James M.: From Hippocrates to Virchow: Reflections on human disease, 277-N
Cooper, Kenneth H.: Controlling cholesterol, 3405-N
Creger, William P., et al. eds.: Annual review of medicine: Selected topics in the clinical sciences, Vol 39, 679-N
Heiby, Walter A.: The reverse effect: How vitamins and minerals promote health and cause disease, 1301-N
Himmelstein, Jay S., and Pransky, Glenn S., ed.: Worker fitness and evaluations, 924-N
Keckley, Paul H.: Market research handbook for health care professionals, 1140-N
Leedy, Jack J., ed.: Poetry as header: Mending the troubled mind, 405-N
Montgomery, John, and Fewer, Willard: Family systems and beyond, 1412-N
Mumey, Jack: Loving alcoholic: Help and hope for codependents, 1037-N
Murphy, Robert F.: The body silent, 913-R
Nikolova, Lilyanna: Treatment with interferential current, ed. 3, 805-R
Pekkanen, John: MD: Doctors talk about themselves, 1412-N
Pendergraph, Garland E.: Handbook of phlebotomy, ed. 2, 679-N
Schroeder, Steven A., Krupp, Marcus A., and Tierney, Lawrence M., eds.: Current medical diagnosis & treatment 1988, 405-N
Stover, Eric, and Nightingale, Elena O., eds.: The breaking of bodies and minds: Torture, psychiatric abuse, and the health professions, 675-R

Whitlock, Evelyn P.: The calcium plus workbook, 1140-N

Orthopedics

Browner, Bruce D., and Edwards, Charles C.: The science and practice of intermedually nailing, 917-R
Foreman, Stephen M., and Croft, Arthur C.: Whiplash injuries: The cervical acceleration/deceleration syndrome, 546-N
The Hastings center: guidelines on the termination of life-sustaining treatment and the care of the dying: A report of the Hasting Center, 81-N
Johnson, Ernest W., ed.: Practical electromyography. ed. 2, 679-N
Kirkaldy-Willis, W.H.: Managing low back pain, 679-N
Post, Melvin: The shoulder: Surgical and nonsurgical management. ed. 2, 405-N
Post, Melvin, ed.: The shoulder: Surgical and nonsurgical treatment. ed. 2, 800-R
Seibel, Michael O.: Foot function: A programmed text, 1301-N
Wu, Kent K.: Techniques in surgical casting and splinting, 679-R

Osteopathic medicine and manual medicine

Barral, Jean-Pierre, and Mercier, Pierre: Visceral manipulation, 924-N
Davidson, Stephen Myles: Manual medicine: A primer, 924-N
Feely, Richard A., ed.: Clinical cranial osteopathy: Selected readings, 679-N
Gershenow, Rochelle P., ed.: The education of the osteopathic physician, 546-N
Schneider, Werner, Jiri Dvorak, and Tritschler, Thomas: Manual medicine therapy, 1301-N
Upledger, John E.: Craniosacral therapy II: Beyond the dura, 924-N

Otolaryngology

Hawthorne, Maurice R., and Bingham, Brian J.G.: Questions and answers in otolaryngology: For revision and self-assessment, 679-N
Hawthorne, Maurice R., and Bingham, Brian J.G.: Questions answers in otolaryngology, 924-N
Katz, Arnold E., ed.: Manual of otolaryngology: Head & neck therapeutics, 546-R
Maran, A.G.D.: Logan Turner's Diseases of the nose, throat and ear. ed. 10, 679-N, 1301-R

Practice management

Brimer, Mark A.: Fundamentals of private practice in physical therapy, 1301-N
Portnoy, Steven, Stromberg, Ross E., and Newbold, Philip A.: Acquiring and enhancing physicians' practices: Strategic issues and implementation guidelines for hospitals and physicians, 1301-N

Pathology

Sheldon, Huntington: Boyd's Introduction to the study of disease. ed. 10, 1140-N
Waller, Bruce, ed.: Contemporary issues in cardiovascular pathology, 405-N

Pharmacology

Appelt, Glenn D, and Appelt, Jennifer M.: Therapeutic pharmacology, 679-N
Niebyl, Jennifer R: Drug use in pregnancy, 277-N
Weibert, Robert T., and Norcross, William A.: Drug interactions index, 1037-N

Physical therapy

Downer, Ann H.: Physical therapy procedures: Selected techniques. ed. 4, ed., 924-N
Grant, Ruth, ed.: Physical therapy fo the cervical and thoracic spine. vol. 17, 679-N

Psychiatry

Adler, Charles S., Morrissey-Adler, Shelia, and Packard, Russel C.: Psychiatric aspects of headache, 539-R
Hoffer, Abram: Common questions on schizophrenia and their answers, 84-N
Gernsbacher, Larry Morton: The suicide syndrome: Origins, manifestations, and alleviation of human self-destructiveness, 405-N
Gold, Mark S.: The good news about depression: Cures and treatments in the new age of psychiatry, 405-N
Gordon, Sol, When living hurts, 408-N
Joan, Polly: Preventing teenage suicide: The living alternative handbook, 405-N, 1137-R
Kaplan, Harold I., and Sadock, Benjamin J.: Clinical psychiatry, 405-N, 917-R
Magid, Ken, and McKelvey Carole A.: High risk: Children without a conscience, 546-N
Meltzer, Herbert Y., ed.: Psychopharmacology: The third generation of progress, 546-N
Soreff, Stephen M, and McNeil, George N., eds.: Handbook of psychiatric differential diagnosis, 546-N
Vaccaro, Jerome V.: Psychiatrists and community mental health centers: A recovery relationship? Vol. 23, Nov. 4, 1037-N
Walker, Percy: The thanatos syndrome, 668-R

Pulmonary-respiratory

Schwarz, Marvin I., and King, Talmadge E.: Interstitial lung disease, 81-N, 808-R

Radiology

Forrester, D.M., and Brown, J.C.: The radiology of joint disease, Vol 2., 800-R
Hudson, Terry M.: Radiologic-pathologic correlation of musculoskeletal lesions, 275-R
Juhl, John H., and Crummy, Andrew B.: Paul and Juhl's Essentials of radiologic imaging. ed. 5, 81-R
Recommendations on limits for exposure to ionizing radiation, 540-R
Stevens, John M, Valentine, Alan R, and Kendall, Brian E.: Computed cranial & spinal imaging: A practical introduction, 546-N
Weissman, Barbara N.W., Sledge, Clement B.: Orthopedic radiology, 419-R

Sports medicine

Blair, Steven N., Painter, Patricia, Pate, Russell R., et al.: American College of Sports Medicine: Resource manual for guidelines for exercise testing and prescription, 1412-R
Cooper, Kenneth H., and Cooper, Mildred: The new aerobics for women, 1412-N
Goldman, Bob and Klatz, Ronald: The 'E' factor, 924-N
Mellion, Morris B., ed.: Office management of sports injuries and athletic problems, 1132-R

Surgery

Ballantyne, John C., and Morrison, Andrew: Rob and Smith's Operative surgery of the ear. ed. 4, 81-R
Dixon, John A.: Surgical application of lasers. ed. 2, 1132-R
Fonseca, Raymond J., and Davis, W. Howard: Reconstructive preprosthetic oral and maxillofacial surgery, 545-R
Georgiade, Nicholas G., et al., eds.: Essentials of plastic, maxillofacial, and reconstructive surgery, 668-R
Hermann, John B., and Wertheimer, Michael D: Case studies in general surgery: Problem-based surgical education, 1140-N
James, Edwin C., Corry, Robert J., and Perry, John F., Jr.: Principles of basic surgery practice, 419-R
Lambert, Wade C., and Doty, Donald B.: Peripheral vascualr surgery, 1296-R
Polk, Hiram C., Jr., Stone, H. Harlan, and Gardner, Bernard: Basic surgery. ed. 3, 264-R
Sigel, Bernard: Diagnostic patient studies in surgery, 1036-R
Stillman, Richard M.: General surgery: Review and assessment, 81-N, 539-R
Way, Lawrence W.: Current surgical diagnosis and treatment, 405-N
Wheeles, Clifford R., Jr.: Atlas of pelvic surgery. ed. 2, 405-N, 913-R
Wind, Gary W., and Rich, Norman W.: Principles of surgical technique: The art of surgery, 1036-R

Urology

King, Lowell R., Stone, Anthony R., and Webster, George D.: Bladder reconstruction and continent urinary diversion, 1412-R
Macfarlane, Michael: Urology for the house officer, 1037-N
Rous, Stephen N., ed.: Urology annual 1988. Vol 2., 679-N

C

CALCIUM PYROPHOSPHATE CRYSTALS
lumbar spinal stenosis associated with hypertrophied ligamentum flavum and calcium pyrophosphate crystal deposition [Drouillard and Mrstik], 1019*
CARCINOMA
dermatofibroma protuberans: report of a case [Norman, Bennett, Drehsen, and Deem], 245*
facial malignant melanoma in a 3-year-old child [Tarnopolsky, Abramsohn, and Min], 1231*
laser vaporization of cervical intraepithelial neoplasia [Stever, Hernandez, and Miyazawa], 1269*
ovarian carcinoma presenting as pneumoperitoneum: report of a case and review of the literature [Fiorelli, Kolman, Minissale, and Barsky], 769*
primary malignant melanoma involving the anorectum [Goldsmith, Gotfried, and Joseph], 653*
CARDIOVASCULAR DISEASE
aqueous heparin therapy: intermittent *v* continuous administration [Freed, Morley, Daly, Giudice, and Steer], 1085*
labetalol in the treatment of elderly patients with mild essential hypertension [Nugent, Bleicher, and Plachetka], 359*
laboratory testing in a hypertension clinic: a reappraisal [Wood and Kroenke], 365*
lipoproteins and cholesterol: biosynthesis and metabolism [Weis], 870*
mitral valve prolapse—a pervasive condition of uncertain etiology [Siebert and Kule], 1099*
the role of hyperlipidemia therapy in preventive care [Bleicher], 1255*

CARDIOVASCULAR SYSTEM
effects of an exercise and stress management program on cardiac patients' psychosocial and vocational status: preliminary study [Liang, Garcia, and McAllister], 1209*
CATHETERIZATION
delayed hydromediastinum after multilumen central venous catheterization [Wehmann and Rongaus], 1118*
CEREBRUM
early-filling cerebral vein [Toffol, Gruener, and Naheedy], 1007*
CERVIX
laser vaporization of cervical intraepithelial neoplasia [Stever, Hernandez, and Miyazawa], 1269*
CESAREAN
management of immediate postcesarean section hemorrhage [Salk, Hernandez, and Miyazawa], 645*
CHOLANGIOHEPATITIS
method of obtaining chronic biliary tree access for long-term management of Oriental cholangiohepatitis: report of a case [Bartkowski, Levesque, and Hoefer], 1015*
CHOLESTEROL
current and new therapy for hypercholesterolemia [Hunninghake], 865*
detection, evaluation, and treatment of hypercholesterolemia in adults: commentary on national cholesterol education program guidelines [Voss], 845*
lipoproteins and cholesterol: biosynthesis and metabolism [Weis], 870*
national cholesterol guidelines enhance treatment [Voss], 843-E
the cholesterol hypothesis and the value of intervention [Brown], 859*
CHOLECYSTOSTOMY
percutaneous cholecystostomy: case report and literature review [Wiener and Flynn], 251*
familial cancers [Freed], 231*
COLOR DOPPLER IMAGING
color Doppler imaging:an overview [Igidbashian, Mitchell, Merton, and Goldberg], 1273*
COMPUTERS
ultrasonic assessment of fetal growth: a computer-assisted protocol [Stankiewicz and Meals], 729*
CONTINUING MEDICAL EDUCATION
AOA continuing medical education [Reuther], 1399*
CRYPTOCOCCOSIS
cryptococcosis: current status [Kitz, Bartizal, and Isaak], 1003*
CRYPTOCOCCUS NEOFORMANS
cryptococcosis: current status [Kitz, Bartizal, and Isaak], 1003*
CUL-DE-SAC
alternate technique for cul-de-sac insufflation for laparoscopy [Kaczmarczyk and Mansi], 755*
CURRICULUM
the McDaniel family: the impact of small-group clinical teaching early in the medical school curriculum [Raub, Baker and Mann], 123*
CYSTITIS
emphysematous pyelonephritis, ureteritis, and cystitis: report of a case [Ginsberg, Weiner, Klaus, Herring, and Goldberg], 895*

D

DEPRESSION
the ability of family practice residents to diagnose depression in outpatients [Henley and Coussens], 118*
DERMATOFIBROMA PROTUBERANS
dermatofibroma protuberans: report of a case [Norman, Bennett, Drehsen, and Deem], 245*
DERMATOLOGY
dermatofibroma protuberans: report of a case [Norman, Bennett, Drehsen, and Deem], 245*
DIABETES
ketoacidosis secondary to oral ritodrine use in a gestational diabetic patient: report of a case [Halpren, Soifer, Haenel, Manara, and Belsky], 241*
DIVERTICULOSIS
jejunal diverticulosis: report of a case and review of the literature [Chester and Thornburg], 511*
DRUGS
hypothesis for prediction of stimulant drug effectiveness utilizing sensory integrative diagnostic methods [Kimball], 757*

E

ECONOMICS
an open letter to our patients [Northup], 989-E
EDITORIALS
an open letter to our patients, 989
AOA takes issue with AMA "paranurse" proposal, 1077
AIDS: a challenge for osteopathic physicians, 93
gauging the importance of personalities in student, intern and resident selection, 340
Hippocrates, Still, and Osler: a shared philosophy, 1204
JAOA education issue highlights profession's growth, 1369
JAOA provides ongoing AIDS education for physicians, 844
mission accomplished? 1077
national cholesterol guidelines enhance treatment, 843
physician participation needed in AIDS education, 92
preventive medicine; osteoporosis, 209
preventable hepatitis B remains health problem, 000
quality control for in-office and independent laboratories, 726
the proper emphasis for AIDS education, 618
treatment or prevention?, 487
EDUCATION
AOA continuing osteopathic medical education [Reuther], 1399*
gauging the importance of personalities in student, intern and resident selection [Allen], 340-E
history of osteopathic medical education accredition [AOA Editorial Department], 1371*
JAOA education issue highlights profession's growth [Williamson], 1369-E
JAOA provides ongoing AIDS education for physicians [D'Alonzo], 844-E
osteopathic medical school finances [Reich], 1383*
osteopathic postdoctoral education in transition [Ward and Baker], 1389*
physician participation needed in AIDS education [Koop], 92-E
selection criteria in postgraduate osteopathic medical education [Bates, Bates, and Tolstrup], 391*
teaching laboratory medicine with a problem-solving approach [Kumar and Fox], 899*
the ability of family practice residents to diagnose depression in outpatients [Henley and Coussens], 118*
the McDaniel family: the impact of small-group clinical teaching early in the medical school curriculum [Raub, Baker, and Mann], 123*
the proper emphasis for AIDS education [Allen], 618-E
time use by trainees in medical education [Wood and Hogan], 396*
undergraduate osteopathic medical education [Reich], 1377*
ELECTROMYOGRAPHY
electromyographic and skin resistance responses to osteopathic manipulative treatment for low-back pain [Ellestad, Nagle, Boesler, and Kilmore], 991*
ESOPHAGUS
spontaneous rupture of esophagus (Boerhaave's syndrome): case report and literature review [Zawisza and Geisler], 787*
EXERCISE
effects of an exercise and stress management program on cardiac patients' psychosocial and vocational status: preliminary study [Liang, Garcia, and McAllister], 1209*

F

FAMILY PRACTICE
the ability of family practice residents to diagnose depression in outpatient [Henley and Coussens], 118*
FETUS
ultrasonic assessment of fetal growth: a computer-assisted protocol [Stankiewicz and Meals], 729*
FINANCES
osteopathic medical school finances [Reich], 1383*
FISTULA
superior mesenteric arteriovenous fistula: case report and literature review [Benedetto and Liszewski], 517*
treatment of gastrocolic fistula with home total parenteral nutrition: report of a case and review of the literature [Kolman, Minissale and Barsky], 114*
traumatic arteriovenous fistula [Haas], 1109*
FOREIGN PRACTICE
the progression of osteopathic medicine internationally: a survey of America-trained DOs practicing abroad [Shadday, Papadeas, and Smith], 1095

G

GASTROINTESTINAL TRACT DISEASE
treatment of gastrocolic fistula with home total parenteral nutrition: report of a case and review of the literature [Kolman, Minissale and Barsky], 114*
GENETICS
familial cancers [Freed], 231*
congenital amniotic band syndrome: report of a familial recurrence [Irving and Doublestein], 891*
GENITOURINARY TRACT
emphysematous pyelonephritis, ureteritis, and cystitis: report of a case [Ginsberg, Weiner, Klaus, Herring, and Goldberg], 895*
GREENFIELD VENA CAVA FILTER
small-bowel obstruction by adhesions secondary to caval perforation by Greenfield vena cava filter [Burandt and Jarski], 1239*
GYNECOLOGY
laser vaporization of cervical intraepithelial neoplasia [Stever, Hernandez, and Miyazawa], 1269*

H

HEALTH CARE
an open letter to our patients [Northup], 989-E
HEART
current and new therapy for hypercholesterolemia [Hunninghake], 865*

detection, evaluation, and treatment of hypercholesterolemia in adults: commentary on the national cholesterol education program guidelines [Voss], 845*
lipoproteins and cholesterol: biosynthesis and metabolsim [Weis], 870*
mitral valve prolapse—a pervasive condition of uncertain etiology [Siebert and Kule], 1099*
the cholesterol hypothesis and the value of intervention [Brown], 859*
HEMORRHAGE
aqueous heparin therapy: intermittent v continuous administration [Freed, Morley, Daly, Giudice, and Steer], 1085*
management of postcesarean section hemorrhage [Salk, Hernandez, and Miyazawa], 645*
HEPARIN
aqueous heparin therapy: intermittent v continuous administration [Freed, Morley, Daly, Giudice, and Steer], 1085*
HEPATITIS B VACCINE
preventable hepatitis b remains health problem [Allen], 1369-E
HIPPOCRATES
Hippocrates, Still, and Osler: a shared philosophy [Allen], 1204-E
Hippocratic thought: its relationship to and between Andrew Taylor Still and Sir William Osler [Suter], 1243*
HUMAN IMMUNODEFICIENCY VIRUS
a mother's viewpoint [Kushnick], 641*
acquired immune deficiency syndrome: an overview [Theriault], 109*
acquired immunodeficiency syndrome and the health care worker [Krachman and D'Alonzo], 749*
AIDS-related psychosocial issues for the patient and physician [Johnson], 234*
AIDS: the general practitioner's concern [Campbell], 371*
neuropsychiatric sequelae of HIV infection [Johnson], 494*
New Jersey's approach to AIDS [Barnish and Condoluci], 1091*
review of current therapy in humman immunodeficiency viral infections [Gulick], 998*
the impact of AIDS in the pediatric and adolescent populations [Dekker], 629*
the physician and AIDS education in the schools [Kane], 635*
the physician's role in the prevention of AIDS [Calabrese and Kelley], 877*
HYDROMEDIASTINUM
delayed hydromediastinum after multilumen central venous catheterization [Wehmann and Rongaus], 1118*
HYPERLIPIDEMIA
the role of hyperlipidemia therapy in preventive care [Bleicher], 1255*
HYPERTENSION
labetalol in the treatment of elderly patients with mild essential hypertension [Nugent, Bleicher, and Plachetka], 359*
laboratory testing in a hypertension clinic: a reappraisal [Wood and Kroenke], 365*

I

INDUSTRIAL MEDICINE
preplacement low-back screening for high-risk areas [Steele and Hoefner], 499*
INFECTIOUS DISEASE
cryptococcosis: current status [Kitz, Bartizal, and Isaak], 1003*
INSUFFLATION
alternate technique for cul-de-sac insufflation for laparoscopy [Kaczmarczyk and Mansi], 755*
INTERNS
gauging the importance of personalities in student, intern and resident selection [Allen], 340-E
osteopathic postdoctoral education in transition [Ward and Baker], 1389*
INTERNSHIPS
selection criteria in postgraduate osteopathic medical education [Bates, Bates, and Tolstrup], 391*

J

JAUNDICE
percutaneous cholecystostomy: case report and literature review [Wiener and Flynn], 251*
JEJUNUM
jejunal diverticulosis: report of a case and review of the literature [Chester and Thornburg], 511*

L

LABETALOL
labetalol in the treatment of elderly patients with mild essential hypertension [Nugent, Bleicher, and Plachetka], 359*
LABOR
management of immediate postcesarean section hemorrhage [Salk, Hernandez, and Miyazawa], 645*
terbutaline in the treatment of preterm labor: a comparison of intravenous and subcutaneous administration [Haspedis and Wolf], 489*
use of vacuum extractor in the community hospital [Fogarty], 1106*
LABORATORIES
quality control for in-office and independent laboratories [Allen], 726-E
LABORATORY MEDICINE
teaching laboratory medicine with a problem-solving approach [Kumar and Fox], 899*
LABORATORY TESTING
comparison of five latex agglutination kits for detecting group A streptococcal antigen [Burdick and Sottile], 219*
LAPAROSCOPY
alternate technique for cul-de-sac insufflation for laparoscopy [Kaczmarczyk and Mansi], 755*
LASERS
combined transurethral electroresection and neodymium:YAG laser therapy for obstructing prostatism [Belkoff and Finkelstein], 1219*
laser vaporization of cervical intraepithelial neoplasia [Stever, Hernandez, and Miyazawa], 1269*
LAURENCE-MOON-BARDET-BIEDL SYNDROME
idiopathic thrombocytopenic purpura in a patient with Laurence-Moon-Bardet-Biedl syndrome [Benson, Shepherd, and Dash], 779*
LIGAMENTUM FLAVUM
lumbar spinal stenosis associated with hypertrophied ligamentum flavum and calcium pyrophosphate crystal deposition [Drouillard and Mrstik], 1019*
LIPID DISORDERS
the role of hyperlipidemia therapy in preventive care [Bleicher], 1255*
LUNGS
diffuse lung infiltration in a homosexual man without AIDS [Pohil, Maple, and D'Alonzo], 115*

M

MAGNETIC RESONANCE IMAGING
magnetic resonance imaging of pelvic masses complicating pregnancy [Lubbers, Izuno, Goff, Johnson, and Sikes], 1010*
MEDICAL PRACTICE
don't "write off" alternative therapies [Geiger], 1338-L
MEDI-NOTES
January, p. 40, alcohol-related need for outpatient medical care; risks from moderate drinking during pregnancy; hepatitis-B vaccination: a cost-benefit analysis; exercise for the elderly; new role for activated charcoal; shoulder pain in elderly patients; usefulness of erythromycin in acute bronchitis; screening of cervical cancer in elderly women; temperature response to antipyretics among febrile illnesses; what adolescents want to discuss with their physicians; cold-induced, silent myocardial ischemia; myoglobin determinations in myocardial infarction; holistic medical education; answers about sugar substitutes; tuberculosis associated with the acquired immunodeficiency syndrome; screening for alcoholism in older patients; the family physician and national health objectives; efficiency and costs of ambulatory services in university hospitals
February, p. 179, update on hepatitis-B vaccination; sickle-cell trait and sudden, exercise-related death; orthostatic hypotension in elderly patients; emotional stress and silent myocardial ischemia; management of bacterial pneumonia in the elderly patient; sleeplessness in young children; appropriate treatment for bleeding hemorrhoids; a team approach to geriatric care; recommending soaps and shampoos for children; skin problems in the elderly
March, p. 316, causes of sudden death in cocaine abusers; single-dose therapy in urinary tract infections; managing obstructive sleep apnea; laser applications in surgery and medicine; minoxidil shows limited effectiveness for hair growth; antibiotics in biliary tract infections; is TB screening needed for hospital employees; abnormal glucose tolerance and risk of coronary artery disease
April, p. 469, unnecessary cardiac pacemaker implants?; video display terminal-related headaches; alternative treatment for pressure sores; office-based antismoking program; lowering hypertension through biofeedback; fecal occult kits detecting colorectal cancer; MRI versatility in spinal diagnosis; improper use of car safety seats; TENS for geriatric chronic pain
May, p. 603, knee arthroplasty in young adults with rheumatoid arthritis, hip fracture, and knee effusion in the elderly; effects of in utero diethylstilbestrol exposure on pregnancy; diagnosing geriatric hip pain; nonsurgical treatment of impotence; improving photoaged skin; management of scoliosis in children; high-dose nicotine chewing gum in smoking cessation; practicing preventive cardiology; balancing drug therapy and surgery; total pelvic exenteration in advanced malignant pelvic disease; nasal nafarelin is alternative to oral danazol for endometriosis; educating physicians on preventive medicine; the changing hospital-physician relationship
June, p. 706, treatment of inflammatory breast cancer; postmenopausal estrogen and coronary artery disease; effects of

Minipress®
(prazosin HCl) Capsules 1 mg, 2 mg, 5 mg

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Brief Summary

MINIPRESS (prazosin hydrochloride) CAPSULES ***For Oral Use***

INDICATIONS AND USAGE: MINIPRESS (prazosin hydrochloride) is indicated in the treatment of hypertension. It is mild to moderate in activity and can be used as the initial agent or in a general treatment program in conjunction with a diuretic and/or other antihypertensive drugs as needed. **CONTRAINDICATIONS:** None known. **WARNINGS: MINIPRESS may cause syncope with sudden loss of consciousness. In most cases this is believed to be due to an excessive postural hypotensive effect, although occasionally the syncopal episode has been preceded by a bout of severe tachycardia with heart rates of 120–180 beats per minute. Syncopal episodes have usually occurred within 30 to 90 minutes of the initial dose of the drug; occasionally they have been reported in association with rapid dosage increases or the introduction of another antihypertensive drug into the regimen of a patient taking high doses of MINIPRESS. The incidence of syncopal episodes is approximately 1% in patients given an initial dose of 2 mg or greater. Clinical trials conducted during the investigational phase of this drug suggest that syncopal episodes can be minimized by limiting the initial dose of the drug to 1 mg, by subsequently increasing the dosage slowly, and by introducing any additional antihypertensive drugs into the patient's regimen with caution (see DOSAGE AND ADMINISTRATION). Hypotension may develop in patients given MINIPRESS who are also receiving a beta-blocker such as propranolol.** If syncope occurs, the patient should be placed in the recumbent position and treated supportively as necessary. This adverse effect is self-limiting and in most cases does not recur after the initial period of therapy or during subsequent dose titration. The patient should also be cautioned to avoid situations where injury could result should syncope occur during the initiation of MINIPRESS therapy. **PRECAUTIONS:** ***Information for Patients:*** Dizziness or drowsiness may occur after the first dose of this medicine. Avoid driving or performing hazardous tasks for the first 24 hours after taking this medicine or when the dose is increased. Dizziness, lightheadedness or fainting may occur, especially when rising from a lying or sitting position. Getting up slowly may help lessen the problem. These effects may also occur if you drink alcohol, stand for long periods of time, exercise, or if the weather is hot. While taking MINIPRESS, be careful in the amount of alcohol you drink. Also, use extra care during exercise or hot weather, or if standing for long periods. Check with your physician if you have any questions. ***Drug Interactions:*** MINIPRESS has been administered without any adverse drug interaction in limited clinical experience to date with the following: (1) cardiac glycosides–digitalis and digoxin; (2) hypoglycemics–insulin, chlorpropamide, phenformin, tolazamide, and tolbutamide; (3) tranquilizers and sedatives–chlordiazepoxide, diazepam, and phenobarbital; (4) antigout–allopurinol, colchicine, and probenecid; (5) antiarrhythmics–procainamide, propranolol (see WARNINGS however), and quinidine; and (6) analgesics, antipyretics and anti-inflammatories–propoxyphene, aspirin, indomethacin, and phenylbutazone. Addition of a diuretic or other antihypertensive agent to MINIPRESS has been shown to cause an additive hypotensive effect. ***Drug/Laboratory Test Interactions:*** False positive results may occur in screening tests for pheochromocytoma in patients who are being treated with prazosin. If an elevated VMA is found, prazosin should be discontinued and the patient retested after a month. ***Laboratory Tests:*** In clinical studies in which lipid profiles were followed, there were generally no adverse changes noted between pre- and post-treatment lipid levels. ***Carcinogenesis, Mutagenesis, Impairment of Fertility:*** No carcinogenic potential was demonstrated in an 18 month study in rats with MINIPRESS (prazosin hydrochloride) at dose levels more than 225 times the usual maximum recommended human dose of 20 mg per day. MINIPRESS was not mutagenic in *in vivo* genetic toxicology studies. In a fertility and general reproductive performance study in rats, both males and females, treated with 75 mg/kg (225 times the usual maximum recommended human dose), demonstrated decreased fertility while those treated with 25 mg/kg (75 times the usual maximum recommended human dose) did not. In chronic studies (one year or more) of MINIPRESS in rats and dogs, testicular changes consisting of atrophy and necrosis occurred at 25 mg/kg/day (75 times the usual maximum recommended human dose). No testicular changes were seen in rats or dogs at 10 mg/kg/day (30 times the usual maximum recommended human dose). In view of the testicular changes observed in animals, 105 patients on long term MINIPRESS therapy were monitored for 17-ketosteroid excretion and no changes indicating a drug effect were observed. In addition, 27 males on MINIPRESS for up to 51 months did not have changes in sperm morphology suggestive of drug effect. ***Usage in Pregnancy:*** Pregnancy Category C: There are no adequate and well controlled studies which establish the safety of MINIPRESS (prazosin HCl) in pregnant women. MINIPRESS should be used during pregnancy only if the potential benefit justifies the potential risk to the mother and fetus. ***Nursing Mothers:*** MINIPRESS has been shown to be excreted in small amounts in human milk. Caution should be exercised when MINIPRESS is administered to a nursing woman. ***Usage in Children:*** Safety and effectiveness in children have not been established. **ADVERSE REACTIONS:** Clinical trials were conducted on more than 900 patients. During these trials and subsequent marketing experience, the most frequent reactions associated with MINIPRESS therapy are: dizziness 10.3%, headache 7.8%, drowsiness 7.8%, lack of energy 6.9%, weakness 6.5%, palpitations 5.3%, and nausea 4.9%. In most instances side effects have disappeared with continued therapy or have been tolerated with no decrease in dose of drug. Less frequent adverse reactions which are reported to occur in 1–4% of patients are: *Gastrointestinal:* vomiting, diarrhea, constipation; *Cardiovascular:* edema, orthostatic hypotension, dyspnea, syncope; *Central Nervous System:* vertigo, depression, nervousness; *Dermatologic:* rash; *Genitourinary:* urinary frequency; *EENT:* blurred vision, reddened sclera, epistaxis, dry mouth, nasal congestion. In addition, fewer than 1% of patients have reported the following (in some instances, exact causal relationships have not been established): *Gastrointestinal:* abdominal discomfort and/or pain, liver function abnormalities, pancreatitis; *Cardiovascular:* tachycardia; *Central Nervous System:* paresthesia, hallucinations; *Dermatologic:* pruritus, alopecia, lichen planus; *Genitourinary:* incontinence, impotence, priapism; *EENT:* tinnitus; *Other:* diaphoresis, fever. Single reports of pigmentary mottling and serous retinopathy, and a few reports of cataract development or disappearance have been reported. **OVERDOSAGE:** Should overdosage lead to hypotension, support of the cardiovascular system is of first importance. Restoration of blood pressure and normalization of heart rate may be accomplished by keeping the patient in the supine position. If this measure is inadequate, shock should first be treated with volume expanders. If necessary, vasopressors should then be used. Renal function should be monitored and supported as needed. Laboratory data indicate MINIPRESS is not dialysable because it is protein bound. **DOSAGE AND ADMINISTRATION:** The dose of MINIPRESS should be adjusted according to individual blood pressure response. ***Initial Dose:*** 1 mg two or three times a day. ***Maintenance Dose:*** Dosage may be slowly increased to a total daily dose of 20 mg given in divided doses. The therapeutic dosages most commonly employed have ranged from 6 mg to 15 mg daily given in divided doses. Doses higher than 20 mg usually do not increase efficacy; however a few patients may benefit from further increases up to a daily dose of 40 mg given in divided doses. After initial titration some patients can be maintained adequately on a twice daily dosage regimen. ***Use With Other Drugs:*** When adding a diuretic or other antihypertensive agent, the dose of MINIPRESS should be reduced to 1 mg or 2 mg three times a day and retitration then carried out. Revised November 1986

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extracorporeal shock wave lithotripsy on the kidneys; transvaginal ultrasound for suspected ectopic pregnancy; supplementary percutaneous oxygen delivery in preterm infants; emergency department ECG screening for suspected myocardial ischemia; dehydration risk factors in nursing home residents; retarded growth in diabetic pregnancy and childhood psychomotor development; cardiopulmonary and gas exchange responses to strenuous exercise on sickle cell trait; long-term overview of aortic valve homografts

July, p. 839, maternal trauma and occult placental abruption; overuse of carotid endarterectomy?; condoms as effective HIV barriers; methotrexate efficacy in asthma patients; significant risk factors for ectopic pregnancy; current management of venous thromboembolism; assessing geriatric mobility dysfunctions; peripheral bone mass measurement and postmenopausal bone loss; factors associated with jaundice in healthy newborns; safe transfer of acutely ill cardiac patients; effects of calcium entry blockers on human platelet aggregation; computers as predictors of abnormal results

August, p. 953, contributing factors to athletes' shin soreness; New York guidelines for HIV testing, counseling; screening older women for cervical cancer; exercise-diet regimen in adolescents with high coronary heart disease-risk; detecting skin cancer; walking with hand weights to burn energy; oral isotretinoin as skin cancer prophylactic?; transcutaneous electrical nerve stimulation in cardiac pacemaker recipients; current recommendations for estrogen replacement therapy; wedge excision as an alternative to mastectomy; review of surgical laser applications; treating the sports-related knee injury; chronic pelvic pain and psychosexual factors; neck pain in the elderly; effects of calcium entry blockers on human platelet aggregation; prehospital autotransfusion during life-threatening hemothorax; almitrine bimesylate improves PaO_2 levels in COPD; sulfamethoxazole and trimethoprim chemoprophylaxis for *Pneumocystis carinii* pneumonia in AIDS; detecting *Trichomonas vaginalis*

September, p. 1068, long-term antihypertensive treatment and its cardiovascular-renal effects; mental stress and silent myocardial ischemia; hormonal supplementation reverses bone loss in postmenopausal women; diagnosing infection in the elderly; epinephrine for older asthmatic adults?; weight-bearing exercises increases lumbar bone mineral content; subcutaneous infusion ports as alternatives to external access devices; smoking and stroke risks in middle-aged women; adenosine beneficial in diagnosis of broad complex tachycardia; alternative management of placenta previa; treatment for a rare variant of acute pancreatitis; penicillamine nephropathy in rheumatoid arthritis; toxic shock syndrome related to insulin infusion pump therapy; HIV infection in hemophiliacs

October, p. 1176, obesity and the autonomic nervous system; indomethacin effects on the fetal ductus arteriosus; early onset hepatic disease and mental, physical development in children; rapid eye test detects drug abuse; brain herniation and diabetic ketoacidosis; balloon aortic valvuloplasty in elderly patients; factors contributing to survival in dialysis patients; endotoxemia and early detection of septicemia in febrile patients; loss of HIV-1 antibodies with evidence of viral infection in asymptomatic homosexual men; intensive *v* less intensive hypertension treatment; noninvasive treatment of gallbladder stones; walking:a healthy exercise alternative; human recombinant granulocyte colony-stimulating factor and chemotherapy induced neutropenia; diuretics and arrhythmia in hypertensives; diabetic nephropathy and platelet inhibitor treatment

November, p. 1348, factors contributing to esophageal fistula healing; coronary artery disease after percutaneous transluminal coronary angioplasty; computer-assisted predictions of myocardial infarction

December, p. 1452, whole bowel irrigation: better antidote than oral activated charcoal?; protection against traveler's diarrhea; efficacy of Nd:YAG laser bronchoscopy; transplant in pulmonary fibrosis; ulcers and surreptitious use of salicylates; effective diagnosis of pneumonia in the ummunocompromised child; heterosexual contact and HIV-related immunologic thrombocytopenic purpura; autism and hypoplastic cerebellar vermis; breast implants complicating mammography; determining respiratory muscle fatigue in acute respiratory failure patients; diabetics and acute cholecystitis; FDA's interpretation of aspirin as primary prevention of myocardial infarction; the connection between renal transplants and accelerated atherosclerosis; relationship between breast cancer and indoor exposure to smoke; United States and United Kingdom (UK) attitudes concerning diagnosis and treatment of coronary disease; postoperative deep vein thrombosis and prophylactics; modifying risk factors after myocardial infarction; aspirin and dipyridamole for short-term prevention of restenosis after PCTA; diagnosing pulmonary embolism in patients with pleuritic chest pain; post stroke management; complex carbohydrate intolerance in infants with protracted diarrhea

MELANOMA
facial malignant melanoma in a 3-year-old child [Tarnopolsky, Abramsohn, and Min], 1231*
primary malignant melanoma involving the anorectum [Goldsmith, Gotfried, and Joseph], 653*
METRIZAMIDE
conduction aphasia following metrizamide myelography [Kassicieh, Drake, Shuttleworth, and Rammohan], 384*
MYELOGRAPHY
conduction aphasia following metrizamide myelography [Kassicieh, Drake, Shuttleworth, and Rammohan], 344*
MUSCLES
electromyographic and skin resistance responses to osteopathic manipulative treatment for low-back pain [Ellestad, Nagle, Boesler, and Kilmore], 991*

N

NATIONAL CHOLESTEROL EDUCATION PROGRAM
detection, evaluation, and treatment of hypercholesterolemia in adults: commentary on national cholesterol education program guidelines [Voss], 845*
NERVE
end-to-side nerve flap for treatment of painful neuroma: a 15-year follow-up [Ashley and Stallings], 621*
NEUROLOGY
reversible multiple cranial nerve palsies in temporal (giant cell) arteritis with normal sedimentation rate: report of a case [Freitag, Diamond, and Solomon], 381*

NEUROMA
end-to-side nerve flap for treatment of painful neuroma: a 15-year follow-up [Ashley and Stallings], 6221*
NEURORADIOLOGY
early-filling cerebral vein [Toffol, Gruener, and Naheedy], 1007*
NURSES
AOA takes issue with AMA 'paranurse' [Allen], 1077-E
NUTRITION
treatment of gastrocolic fistula with home total parenteral nutrition: report of a case and review of the literature [Kolman, Minissale, and Barsky], 114*

O

OBSTETRICS
ketoacidosis secondary to oral ritodrine use in a gestational diabetic patient: report of a case [Halpren, Soifer, Haenel, Manara, and Belsky], 241*
magnetic resonance imaging of pelvic masses complicating pregnancy [Lubbers, Izuno, Goff, Johnson, and Sikes], 1010*
management of immediate postcesarean section hemorrhage [Salk, Hernandez, and Miyazawsa], 645*
terbutaline in the treatment of preterm labor: a comparison of intravenous and subcutaneous administration [Haspedis and Wolf], 489*
ultrasonic assessment of fetal growth: a computer-assisted protocol [Stankiewicz and Meals], 729*
use of vacuum extractor in the community hospital [Fogarty], 1106*
OCCUPATIONAL MEDICINE
low-back injuries and osteopathic medicine: practicing what we preach [Wyatt], 1338-L
preplacement low-back screening for high-risk areas [Steele and Hoefner], 499*
ORTHOPEDICS
unilateral interfacetal dislocation in the lower cervical spine [Gideon and Mulkey], 1223*
OSLER
Hippocrates, Still, and Osler: a share philosophy [Allen], 1204-E
OSTEOPATHIC MANIPULATIVE TREATMENT
electromyographic and skin resistance responses to osteopathic manipulative treatment for low-back pain [Ellestad, Nagle, Boesler, and Kilmore], 991*
mission accomplished [Allen] 1077-E
segmental definition: Part I. a focal point for diagnosis of somatic dysfunction [Johnston], 99*
segmental definition: Part II. application of an indirect method in osteopathic manipulative treatment [Johnston], 211*
segmental definition: III. definitive basis for distinguishing somatic findings of visceral reflex origin [Johnston], 347*
OSTEOPATHIC MEDICINE
electromyographic and skin resistance responses to osteopathic manipulative treatment for low-back pain [Ellestad, Nagle, Boesler, and Kilmore], 991*
Hippocrates, Still, and Osler: a shared philosophy [Allen], 1204-E
Hippocratic thought: its relationship to and between Andrew Taylor Still and Sir William Osler [Suter], 1243*
low-back injuries and osteopathic medicine: practicing what we preach [Wyatt], 1338-L
mission accomplished [Allen], 1077-E
segmental definition: Part I. a focal point for diagnosis of somatic dysfunction [Johnston], 99*
segmental definition: Part II. application of an indirect method in osteopathic manipulative treatment [Johnston], 211*
segmental definition: III. definitive basis for distinguishing somatic findings of visceral reflex origin [Johnston], 347*
the progression of osteopathic medicine internationally: a survey of America-trained DOs practicing abroad [Shadday, Papadeas, and Smith], 1095*
OSTEOPOROSIS
preventive medicine; osteoporosis [Allen], 209-E
treatment or prevention [Allen], 487-E
OVARY
ovarian carcinoma presenting as pneumoperitoneum: report of a case and review of the literature [Fiorelli, Kolman, Minissale, and Barsky], 769*

P

PANIC DISORDER
pitfalls in the management of panic disorder [Tobe], 507*
PARANURSE
AOA takes issue with AMA 'paranurse' proposal [Allen],1077-E
PATIENT HEALTH GUIDE
a prescription for taking medicine properly [Reich], 1421
arthroscopy: A leg up on knee surgery [Reich], 132
dyslexia, a lesson in reading disabilities [Reich], 1317
Ear disorders in children [Reich], 283
Focusing on contact lenses [Reich], 1045
Involuntary urine loss: Dispelling the myths [Reich], 1153
Mysterious premenstrual syndrome (PMS) [Reich], 935
Sun raises skin cancer risks [Reich], 813
Taking charge of your migraine [Reich], 561
Taking the lid off eating disorders [Reich], 685
The driving force of pacemakers [Reich], 441
PEDIATRICS
a mother's viewpoint [Kushnick], 641*
facial malignant melanoma in a 3-year-old child [Tarnopolsky, Abramsohn, and Min], 1231*
hypothesis for prediction of stimulant drug effectiveness utilizing sensory integrative diagnostic methods [Kimball], 757*
the impact of AIDS in the pediatric and adolescent populations [Dekker], 629*
PELVIS
magnetic resonance imaging of pelvic masses complicating pregnancy [Lubbers, Izuno, Goff, Johnson, and Sikes], 1010*
PERSONALITIES
gauging the importancce of personalities in student, intern and resident selection [Allen], 340-E
PHARYNGITIS
comparison of five latex agglutination kits for detecting group A streptococcal antigen [Burdick and Sottile], 219*
PLASTIC SURGERY
end-to-side nerve flap for treatment of painful neuroma: a 15-year follow-up [Ashley and Stallings], 621*
PNEUMOPERITONEUM
ovarian carcinoma presenting as pneumoperitoneum: report of a case and review of the literature [Fiorelli, Kolman, Minissale, and Barsky], 769*
PREGNANCY
ketoacidosis secondary to oral ritodrine use in a gestational diabetic patient: report of a case [Halpren, Soifer, Haenel, Manara, and Belsky], 241*
magnetic resonance imaging of pelvic masses complicating pregnancy [Lubbers, Izuno, Goff, Johnson, and Sikes], 1010*
terbutaline in the treatment of preterm labor: a comparison of intravenous and subcutaneous administration [Haspedis and Wolf], 489*
ultrasonic assessment of fetal growth: a computer-assisted protocol [Stankiewicz and Meals], 729*
use of the vacuum extractor in the community hospital [Fogarty], 1106*
PREVENTION
preventable hepatitis B remains health problem [Allen], 000-E
the role of hyperlipidemia therapy in preventive care [Bleicher], 1255*
PREVENTIVE MEDICINE

preventive medicine; osteoporosis [Allen], 209-E
treatment or prevention? [Allen], 487-E
PROSTATE GLAND
combined transurethral electroresection and neodymium:YAG laser therapy for obstructing prostatism [Belkoff and Finkelstein], 1219*
PSYCHIATRY
AIDS-related psychosocial issues for the patient and physician [Johnson], 234*
neuropsychiatric sequelae of HIV infection [Johnson], 494*
pitfalls in the management of panic disorder [Tobe], 507*
PULMONARY DISEASE
diffuse lung infiltration in a homosexual man without AIDS [Pohil, Maple, and D'Alonzo], 1115*
PURPURA
idiopathic thrombocytopenic purpura in a patient with Laurence-Moon-Bardet-Biedl syndrome [Benson, Shepherd, and Dash], 779*
PYELONEPHRITIS
emphysematous pyelonephritis, ureteritis, and cystitis: report of a case [Ginsberg, Weiner, Klaus, Herring, and Goldberg], 895*

Q

QUALITY CONTROL
quality control for in-office and independent laboratories [Allen], 726-E

R

RADIOLOGY
color Doppler imaging: an overview [Igidbashian, Mitchell, Merton, and Goldberg], 1273*
early-filling cerebral vein [Toffol, Gruener, and Naheedy], 1007*
RECTUM
primary malignant melanoma involving the anorectum [Goldsmith, Gotfried, and Joseph], 653*
RESIDENCIES
gauging the importance of personalities in student, intern and resident selection [Allen], 340-E
osteopathic postdoctoral education in transition, 1389*
selection criteria in postgraduate osteopathic medical education [Bates, Bates, and Tolstrup], 391*
RITODRINE
ketoacidosis secondary to oral ritodrine use in a gestational diabetic patient: report of a case [Halpren, Soifer, Haenel, Manara, and Belsky], 241*

S

SIR WILLIAM OSLER
Hippocratic thought: its relationship to and be-

Micronase®

Tablets (glyburide) **Usual starting dosage 2.5 mg-5 mg once a day**

CONTRAINDICATIONS: MICRONASE Tablets are contraindicated in patients with: 1. Known hypersensitivity or allergy to the drug. 2. Diabetic ketoacidosis, with or without coma. This condition should be treated with insulin. 3. Type I diabetes mellitus, as sole therapy.

SPECIAL WARNING ON INCREASED RISK OF CARDIOVASCULAR MORTALITY: The administration of oral hypoglycemic drugs has been reported to be associated with increased cardiovascular mortality as compared to treatment with diet alone or diet plus insulin. This warning is based on the study conducted by the University Group Diabetes Program (UGDP), a long-term prospective clinical trial designed to evaluate the effectiveness of glucose-lowering drugs in preventing or delaying vascular complications in patients with noninsulin-dependent diabetes. The study involved 823 patients who were randomly assigned to one of four treatment groups (Diabetes, 19 [Suppl 2]: 747-830, 1970).

UGDP reported that patients treated for 5 to 8 years with diet plus a fixed dose of tolbutamide (1.5 grams per day) had a rate of cardiovascular mortality approximately 2½ times that of patients treated with diet alone. A significant increase in total mortality was not observed, but the use of tolbutamide was discontinued based on the increase in cardiovascular mortality, thus limiting the opportunity for the study to show an increase in overall mortality. Despite controversy regarding the interpretation of these results, the findings of the UGDP study provide an adequate basis for this warning. The patient should be informed of the potential risks and advantages of MICRONASE and of alternative modes of therapy.

Although only one drug in the sulfonylurea class (tolbutamide) was included in this study, it is prudent from a safety standpoint to consider that this warning may apply to other oral hypoglycemic drugs in this class, in view of their close similarities in mode of action and chemical structure.

PRECAUTIONS: General—*Hypoglycemia:* All sulfonylureas are capable of producing severe hypoglycemia. Proper patient selection and dosage and instructions are important to avoid hypoglycemic episodes. Renal or hepatic insufficiency may increase the risk of serious hypoglycemic reactions. Elderly, debilitated or malnourished patients, and those with adrenal or pituitary insufficiency, are particularly susceptible to the hypoglycemic action of glucose-lowering drugs. Hypoglycemia may be difficult to recognize in the elderly and in people who are taking beta-adrenergic blocking drugs. Hypoglycemia is more likely to occur when caloric intake is deficient, after severe or prolonged exercise, when alcohol is ingested, or when more than one glucose-lowering drug is used.

Loss of Control of Blood Glucose: In diabetic patients exposed to stress such as fever, trauma, infection or surgery, a loss of control may occur. It may then be necessary to discontinue MICRONASE and administer insulin. Adequate adjustment of dose and adherence to diet should be assessed before classifying a patient as a secondary failure. *Information for Patients:* Patients should be informed of the potential risks and advantages of MICRONASE and of alternative modes of therapy. They also should be informed about the importance of adherence to dietary instructions, of a regular exercise program, and of regular testing of urine and/or blood glucose. The risks of hypoglycemia, its symptoms and treatment, and conditions that predispose to its development should be explained to patients and responsible family members. Primary and secondary failure should also be explained.

Laboratory Tests: Response to MICRONASE Tablets should be monitored by frequent urine glucose tests and periodic blood glucose tests. Measurement of glycosylated hemoglobin levels may be helpful in some patients.

Drug Interactions: The hypoglycemic action of sulfonylureas may be potentiated by certain drugs including nonsteroidal anti-inflammatory agents and other drugs that are highly protein bound, salicylates, sulfonamides, chloramphenicol, probenecid, coumarins, monoamine oxidase inhibitors, and beta adrenergic blocking agents.

Certain drugs tend to produce hyperglycemia and may lead to loss of control. These drugs include the thiazides and other diuretics, corticosteroids, phenothiazines, thyroid products, estrogens, oral contraceptives, phenytoin, nicotinic acid, sympathomimetics, calcium channel blocking drugs, and isoniazid.

A potential interaction between oral miconazole and oral hypoglycemic agents leading to severe hypoglycemia has been reported.

Carcinogenesis, Mutagenesis, and Impairment of Fertility: Studies in rats at doses up to 300 mg/kg/day for 18 months showed no carcinogenic effects. Glyburide is nonmutagenic when studied in the Salmonella microsome test (Ames test) and in the DNA damage/alkaline elution assay.

Pregnancy: *Teratogenic effects:* Pregnancy Category B. Reproduction studies in rats and rabbits have revealed no evidence of impaired fertility or harm to the fetus due to glyburide. There are no adequate and well controlled studies in pregnant women. This drug should be used during pregnancy only if clearly needed. Insulin should be used during pregnancy to maintain blood glucose as close to normal as possible. *Nonteratogenic Effects:* Prolonged severe hypoglycemia (4 to 10 days) has been reported in neonates born to mothers who were receiving a sulfonylurea drug at the time of delivery. MICRONASE should be discontinued at least two weeks before the expected delivery date.

Nursing Mothers: Some sulfonylurea drugs are known to be excreted in human milk. Insulin therapy should be considered.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: Hypoglycemia: See Precautions and Overdosage sections. **Gastrointestinal Reactions:** Cholestatic jaundice and hepatitis may occur rarely; MICRONASE Tablets should be discontinued if this occurs. Gastrointestinal disturbances (nausea, epigastric fullness, and heartburn) occurred in 1.8% of patients during clinical trials. They were the most commonly reported adverse reactions. They tend to be dose related and may disappear when dosage is reduced. Liver function abnormalities have been reported. **Dermatologic Reactions:** Allergic skin reactions, e.g., pruritus, erythema, urticaria, and morbilliform or maculopapular eruptions occurred in 1.5% of patients during trials. These may be transient and may disappear despite continued use of MICRONASE; if skin reactions persist, the drug should be discontinued. Porphyria cutanea tarda and photosensitivity reactions have been reported with sulfonylureas. **Hematologic Reactions:** Leukopenia, agranulocytosis, thrombocytopenia, hemolytic anemia, aplastic anemia, and pancytopenia have been reported with sulfonylureas. **Metabolic Reactions:** Hepatic porphyria and disulfiram-like reactions have been reported with sulfonylureas; however, hepatic porphyria has not been reported with MICRONASE and disulfiram-like reactions have been reported very rarely. Cases of hyponatremia have been reported with glyburide and all other sulfonylureas, most often in patients who are on other medications or have medical conditions known to cause hyponatremia or increase release of antidiuretic hormone. (SIADH) secretion has been reported with certain other sulfonylureas, and it has been suggested that these sulfonylureas may augment the peripheral (antidiuretic) action of ADH and/or increase release of ADH.

OVERDOSAGE: Overdosage of sulfonylureas, including MICRONASE Tablets, can produce hypoglycemia. If hypoglycemic coma is diagnosed or suspected, the patient should be given a rapid intravenous injection of concentrated (50%) glucose solution. This should be followed by a continuous infusion of a more dilute (10%) glucose solution at a rate which will maintain the blood glucose at a level above 100 mg/dL. Patients should be closely monitored for a minimum of 24 to 48 hours, since hypoglycemia may recur after apparent clinical recovery.

Maximum Dose: Daily doses of more than 20 mg are not recommended.

Dosage Interval: Once-a-day therapy is usually satisfactory. Some patients, particularly those receiving more than 10 mg daily, may have a more satisfactory response with twice-a-day dosage.

Specific Patient Populations: MICRONASE is not recommended for use in pregnancy or for use in children. In elderly patients, debilitated or malnourished patients, and patients with impaired renal or hepatic function, the initial and maintenance dosing should be conservative to avoid hypoglycemic reactions. (See Precautions Section).

For additional product information see your Upjohn representative.

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B-5-S May 1988 J-8274

tween Andrew Taylor Still and Sir William Osler [Suter], 1243*

SOMATIC DYSFUNCTION
segmental definition: Part I. a focal point for diagnosis of somatic dysfunction [Johnston], 99*
segmental definition: Part II. application of an indirect method in osteopathic manipulative treatment [Johnston], 211*
segmental definition: III. definitive basis for distinguishing somatic findings of visceral reflex origin [Johnston], 347*

SPINE
conduction aphasia following metrizamide myelography [Kassicieh, Drake, Shuttleworth, and Rammohan], 384*
lumbar spinal stenosis associated with hypertrophied ligamentum flavum and calcium pyrophosphate crystal deposition [Drouillard and Mrstik], 1019*
unilateral interfacetal dislocation in the lower cervical spine [Gideon and Mulkey], 1223*

STENOSIS
lumbar spinal stenosis associated with hypertrophied ligamentum flavum and calcium pyrophosphate crystal deposition [Drouillard and Mrstik], 1019*

STILL
Hippocrates, Still, and Osler; a shared philosophy [Allen], 1204

STIMULANTS
hypothesis for prediction of stimulant drug effectiveness utilizing sensory integrative diagnostic methods [Kimball], 757*

STREPTOCOCCUS
comparison of five latex agglutination kits for detecting group A streptococcal antigen [Burdick and Sottile], 219*

STRESS
effects of an exercise and stress management program on cardiac patients' psychosocial and vocational status: preliminary study [Liang, Garcia, and McAllister], 1209*

SURGERY
percutaneous cholecystostomy: case report and literature review [Wiener and Flynn], 251*
superior mesenteric arteriovenous fistula: case report and literature review [Benedetto and Liszewski], 517*

T

TERBUTALINE
terbutaline in the treatment of preterm labor: a comparison of intravenous and subcutaneous administration [Haspedis and Wolf], 489*

THROMBOUS
aqueous heparin therapy: intermittent v continuous administration [Freed, Morley, Daly, Giudice, and Steer], 1085*

THYROTOXICOSIS
choriocarcinoma-induced thyrotoxicosis: report of a case and review of the literature [Fierro and Freeman], 525*

TRAUMA
superior mesenteric arteriovenous fistula: case report and literature review [Benedetto and Liszewski], 517*

U

ULTRASONOGRAPHY
color Doppler imaging: an overview [Igidbashian, Mitchell, Merton, and Goldberg], 1273*
ultrasonic assessment of fetal growth: a computer-assisted protocol [Stankiewicz and Meals], 729*

URETERITIS
emphysematous pyelonephritis, ureteritis, and cystitis: report of a case [Ginsberg,

Weiner, Klaus, Herring, and Goldberg], 895*
UROLOGY
combined transurethral electroresection and neodymium:YAG laser therapy for obstructing prostatism [Belkoff and Finkelstein], 1219*
emphysematous pyelonephritis, ureteritis, and cystitis: report of a case [Ginsberg, Weiner, Klaus, Herring, and Goldberg], 895*

V

VACUUM EXTRACTOR
use of the vacuum extractor in the community hospital [Fogarty], 1106*
VALVE
mitral valve prolapse—a pervasive condition of uncertain etiology [Siebert and Kule], 1099*
VEIN
early-filling cerebral vein [Toffol, Gruener, and Naheedy], 1007*
traumatic arteriovenous fistula [Haas], 1109*
VENA CAVA
small-bowel obstruction by adhesions secondary to caval perforation by Greenfield vena cava filter [Burandt and Jarski], 1239*
VERTEBRAE

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